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Eldora Ellison
Helene Carlson
Sterne, Kessler, Goldstein & Fox PLLC
1100 New York Ave., NW
Washington, DC 20005

In Re: Patent Term Extension
Application for U.S. Patent No. 7,008,765
Filed: April 11, 2012

mailed
JUL 31 2012
OPLA

NOTICE OF INFORMALITIES

The above-identified application for patent term extension (PTE application) has been accorded a filing date of April 11, 2012, however, certain regulatory requirements have not been fulfilled.

(1) The PTE application was not filed by a party recognized under 37 C.F.R. 1.730.

(2) Section 1.740(a)(9) of title 37 of the Code of Federal Regulations requires,

> A statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claim reads on:
>
> (i) The approved product, if the listed claims include any claim to the approved product;
>
> (ii) The method of using the approved product, if the listed claims include any claim to the method of using the approved product; and
>
> (iii) The method of manufacturing the approved product, if the listed claims include any claim to the method of manufacturing the approved product. . . .

See 37 C.F.R. 1.740(a)(9)(i)-(iii).

First, 37 C.F.R. 1.730 requires that an application for patent term extension be filed by "the owner of record or its agent. . . ." 37 C.F.R. 1.730(a). When an agent of the patent owner is filing the application for patent term extension, then the signature requirements must fulfill 37 C.F.R. 1.730(c). Here, the signature on the submission of the application is from an agent of the owner. However, R. William Bowen, Jr. is not a registered practitioner acting on behalf of the agent of the patent owner. To properly comply with 37 C.F.R.1.730(c), Applicant must furnish a duplicate application properly signed or ratify the application already on file. This means a single properly signed copy.

Second, the manner of showing how the patent claims the product, in reference of claim 6, solely indicates that the approved product contains "an isolated nucleic acid molecule. . . ."and repeats verbatim the language of claim 6 without any specificity as to which of the recited alternate sequences of claim 6 are present in the approved product. While it is understood, from page 4 of the PTE application, that the sequence information regarding the molecules is proprietary

information of the Marketing Applicant, assessment of compliance with the applicable regulatory provisions of 37 C.F.R. 1.740-et seq. cannot be completed without such information. Applicant's attention is directed to MPEP § 724.02 which sets forth procedures for submission of proprietary information.

Applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, to comply with the requirements enumerated above. Extensions of time under 37 C.F.R. 1.136(a) are not applicable to this time period.

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-0100
Attn: Office of Patent Legal Administration

Telephone inquiries related to this notice should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: PROGENSA® (PCA3 Assay)
Docket No.: FDA-2012-E-